




Certificate of Analysis

SALSA® MLPA® Probemix P378 MUTYH

Catalogue #	P378-25R, P378-50R, P378-100R	
Product name	Probemix P378 MUTYH	
LOT	D1-1217	
	25, 50, or 100 reactions.	
Shipping conditions	Dry ice or cooling elements.	
	Store upon arrival between -25 °C and -15 °C.	
	Expiration date: December 2022, when stored at recommended conditions. This product should not be frozen/thawed more than 25 times.	
Use	To detect deletions or duplications in specific regions of the human <i>GREM1</i> and <i>SCG5</i> genes and to detect deletions or duplications as well as the presence of the p.Y179C and p.G396D point mutations in the human <i>MUTYH</i> gene, for confirming a potential cause and clinical diagnosis for MUTYH-Associated Polyposis (MAP) and Hereditary Mixed Polyposis Syndrome (HMPS). This probemix is designed for use only in combination with SALSA MLPA reagent kits as described in the MLPA General Protocol.	
Quality Test 1	Sufficient distance between peaks, absence of extra or shoulder peaks, completeness of hybridisation of each individual probe, as tested on Applied Biosystems 3130 and Beckman GeXP sequencers.	PASS
Quality Test 2	Standard deviation of each individual probe is <0.10, when tested on 23 different DNA samples of healthy individuals, extracted by various methods.	PASS
Quality Test 3	Standard deviation of each individual probe, tested on a single DNA sample under various experimental conditions, meeting reaction-specific criteria. Conditions tested include: pipetting errors; evaporation; deviating thermocycler temperatures; presence of salts (affecting DNA sample denaturation) or presence of impurities in the DNA sample.	PASS
Quality Test 4	No DNA controls resulted in only 5 major peaks shorter than 121 nucleotides (nt): 4 Q fragments at 64, 70, 76 and 82 nt, and one 19 nt peak corresponding to the unused portion of the fluorescent PCR primer. Non-specific peaks longer than 121 nt AND with a height >25% of the median of the 4 Q fragments were not observed. Note: peaks below this 25% threshold are not expected to affect MLPA reactions when sufficient (50-250 ng) sample DNA is used.	PASS

EUROPE*: FOR IN VITRO DIAGNOSTIC (IVD) USE. THIS PRODUCT IS CE MARKED.
ALL OTHER COUNTRIES: FOR RESEARCH USE ONLY (RUO).

*comprising EU member states, EU member states candidates, and members of the European Free Trade Association (EFTA). The product is for RUO in all other countries within Europe.

None of the ingredients are derived from humans, animals, or pathogenic bacteria. Based on the concentrations present, none of the ingredients are hazardous as defined by the Hazard Communication Standard. **A Safety Data Sheet (SDS) is not required for these products:** none of the preparations contain dangerous substances (as per Regulation (EC) No 1272/2008 [EU-GHS/CLP] and amendments) at concentrations requiring distribution of an SDS (as per Regulation (EC) No 1272/2008 [EU-GHS/CLP] and 1907/2006 [REACH] and amendments). If spills occur, clean with water and follow appropriate site procedures.

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More information: www.mlpa.com; www.mlpa.eu

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SALSA® MLPA® probemix P378-D1 MUTYH sample picture

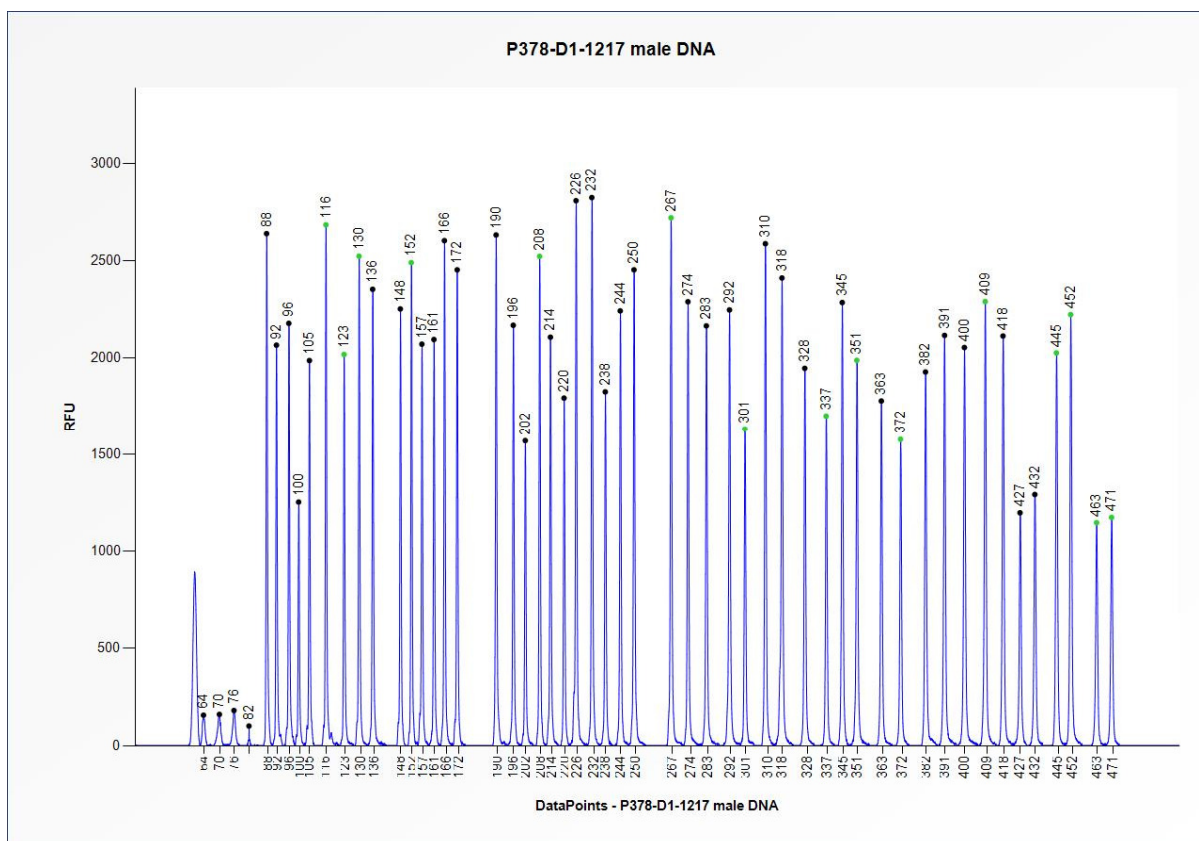


Figure 1. Capillary electrophoresis pattern from a sample of approximately 50 ng human male control DNA analysed with SALSA MLPA probemix P378 MUTYH (D1-1217).

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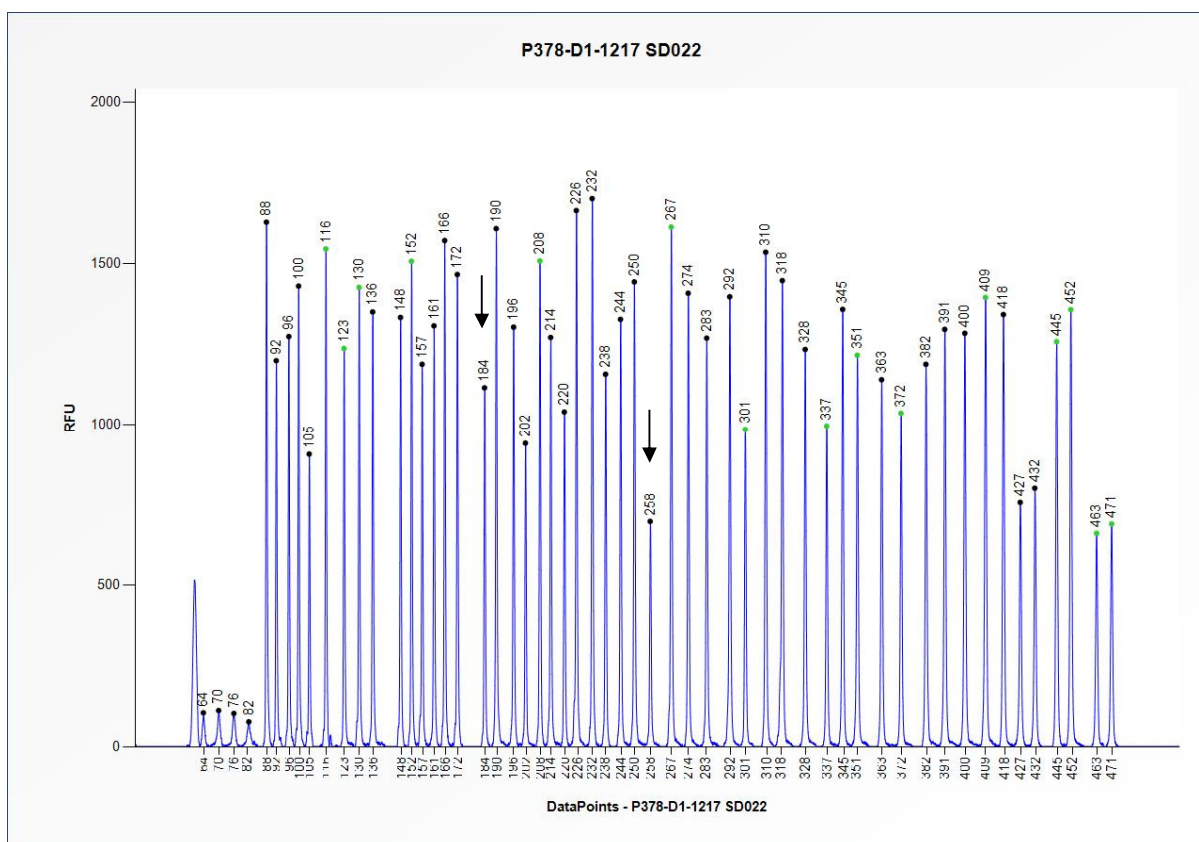


Figure 2. Capillary electrophoresis pattern of SALSA Binning DNA SD022 (approximately 50 ng) analysed with SALSA MLPA probemix P378 MUTYH (D1-1217). The locations of the p.Y179C and the p.G396D mutation specific probes at respectively 184 nt and 258 nt are indicated.

This lot was certified by MRC-Holland on 20 February 2018.

This certificate is a declaration of analysis at the time of the manufacturing process. All assays were run in compliance with manufacturer's instructions for use.

Implemented changes in the COA

Version 01- 23 February 2018 (03)

- Not applicable, new document.